DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
DRUG TESTING ADVISORY BOARD

December 13 - 14, 2005

The Drug Testing Advisory Board was convened for its meeting at 8:30 a.m. on December 13, 2005, in the SAMHSA Building (Sugarloaf Room), 1 Choke Cherry Road, Rockville, Maryland.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on December 13 from 8:30 a.m. to 9:50 a.m. The meeting was closed to the public on December 13 from 9:50 a.m. until adjournment on December 14 at 11:45 a.m. to develop the final revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs and specific laboratory certification issues.

Board members present:

Robert Stephenson II, Chairman
Dr. Alberto Gutierrez
Dr. Estela Estape
Dr. Jennifer Collins
Dr. Henry Nipper
Lisa Tarnai
Dr. Frederick Fochtman
Dr. William Ferguson Reid
Ann Marie Gordon

Executive Secretary present:

Dr. Donna Bush, Division of Workplace Programs (DWP), CSAP

Others present for all or a portion of the meeting were:

Dr. Walter Vogl, DWP, CSAP
Charles LoDico, DWP, CSAP
Ron Flegel, DWP, CSAP
Dr. John Mitchell, RTI International
Dr. Mike Baylor, RTI International
Dr. Craig Sutheimer, RTI International
Susan Crumpton, RTI International
George Ellis, Department of Transportation (DOT)
Dr. Yale Caplan, DOT Consultant

TOPICS DISCUSSED IN OPEN SESSION

Note: The transcript for the open session is available on the Internet at: http://workplace.samhsa.gov

Opening Remarks

Mr. Stephenson convened the open session of the Board meeting.

Four new Board members were introduced. The new members are Dr. Henry Nipper (Director of Chemistry and Toxicology, Department of Pathology, Creighton University Medical Center), Lisa Tarnai (Laboratory Director, Kroll Scientific Testing Laboratory), Dr. Estela Estape (Dean, College of Health Related Professions, University of Puerto Rico), and Dr. Jennifer Collins (Laboratory Director, MedTox Laboratories).

HHS Update

Dr. Bush stated that Sciteck Clinical Laboratories was suspended on November 14, but Sciteck requested a Federal court in North Carolina to issue a temporary restraining order (TRO). The Federal court issued a TRO on November 21 and a hearing was scheduled for November 29. Based on the information presented and discussed at the hearing, the judge denied Sciteck's motion for a preliminary injunction and vacated the TRO on December 1. The suspension was made retroactive to November 14 and the Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory as described in the Mandatory Guidelines will be used to address any appeal Sciteck may file with regard to its suspension and proposed revocation.

DOT Update

Mr. Ellis (DOT) stated that DOT released its notice of proposed rulemaking (NPRM) for urine specimen validity testing (SVT) on October 31. The notice proposes to make urine SVT mandatory rather than authorized. Currently, DOT regulated employers can choose to have specimen validity tests conducted on their specimens. However, if they choose to do so, DOT requires them to ensure that the laboratories conduct the SVTs in accordance with HHS requirements.

The NPRM also provides guidance for medical review officers (MRO). DOT understands the increased burden that exists for interpreting SVT results, whether it is for adulterated, substituted or invalid specimens. The NPRM describes how DOT wants MROs to handle these kinds of specimens.

Finally, the NPRM asks a lot of questions because this is a complex issue, and DOT is hoping that many public comments will be submitted. The public comment period ends December 31.

Finally, on our Website, we have an automated e-mail notification system. When something

new happens or when we issue a newsletter, you will automatically receive the information by e-mail. There is a button on the DOT Website to sign up for this service.

Mr. Stephenson stated that we are still going through the process of revising the Mandatory Guidelines to include testing alternative specimens. This process has taken more than a year from when the public comment ended. The comments were reviewed internally with the same sense of reasonableness and administrative review expected of DOT for its NPRM to ensure that the Guidelines will be scientifically accurate and legally defensible. The process of editing, review, clearance, and agreement has been completed. I cannot give you a timeline for the next step, but we are continuing to move closer to getting the final revised Guidelines signed by the Secretary. I can assure you that anyone associated with this process has made every effort to do his or her part to move the document to the next administrative level of review.

NLCP Website Initiative

Dr. John Mitchell (RTI International) described the new Website being developed for the National Laboratory Certification Program (NLCP). The Website will be a secure Website that the certified laboratories can use to submit not only the results for their quarterly performance testing samples, but also to submit all information required for the inspection program. The Website will also be used to maintain the files associated with all laboratory correspondence.

Dr. Mitchell believes the Website will be ready for use beginning in January 2006. Initially, RTI will enter the laboratory data, request the laboratories to verify it, and then instruct the laboratories to make all changes and future submissions electronically.

Public Comment

Mr. Philip Haber (Licensed Professional Counselor) provided a statement on behalf of the International Paruresis Association reiterating its request that SAMHSA allow an individual who is unable to provide a urine specimen due to paruresis (shy bladder) to request that an alternative specimen be collected (e.g., hair or oral fluid).

The open session ended at 9:50 a.m.

TOPICS DISCUSSED IN CLOSED SESSION

The Board approved the Minutes for the September 7 -8 meeting.

The Board prepared the final revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Program (69 FR 19673).

Other topics discussed by the Board included specific Federal agency specimen results, medical review officer interpretations of Federal agency specimen test results, issues associated with various laboratory inspections, and analytical instrumentation issues.

Adjournment

The meeting adjourned at 11:45 a.m. on December 14.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

/signed/

Donna M. Bush, Ph.D., D-ABFT
Executive Secretary, DTAB

/signed/

Robert L. Stephenson II, M.P.H.
Chair, DTAB

These minutes will be formally considered by the Board at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.